DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 21, 2006

W/L 02-07

Natasha Trenev, President
Natren Inc.
3105 Willow Lane
Westlake Village, CA 86441

Dear Ms. Trenev:

This letter concerns your marketing of the products, Gy-Na-Tren Vaginal Health Solution (Gy-Na-Tren), Life Start, CanineDophilus, FelineDophilus, and EquiFlora on your website, www.natren.com. According to these products' labeling, including information on your website, www.natren.com, Gy-Na-Tren (oral and vaginal capsules), Life Start, and CanineDophilus are drugs within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g), because they are intended to prevent, treat, or cure disease conditions in humans and animals. FelineDophilus, and EquiFlora are drugs because they are intended to affect the structure or function of animal bodies. CanineDophilus is also intended to affect the structure or function of the animal body. In addition, Gy-Na-Tren (vaginal capsules) is intended to affect the structure or function of the human body. The marketing of these products violates various provisions in the Federal Food, Drug, and Cosmetic Act as described below.

HUMAN DRUG PRODUCTS

Gy-Na-Tren Vaginal Health Solution (Gy-Na-Tren)

Your human drug product, Gy-Na-Tren, is a kit containing one 14-capsule bottle of an oral preparation and one 14-capsule bottle of a vaginal preparation. Both preparations bear the name MEGA DOPHILUS, are labeled as dietary supplements, and contain the ingredient "*Lactobacillus acidophilus.*"

The following statements from your package labeling document the intended use of the Gy-Na-Tren product (both vaginal and oral capsules) for yeast overgrowth, a disease condition:

Outer carton labeling:

- "Clinically Proven . . . Safe, effective, natural beneficial flora *L. acidophilus*, NAS super strain in veggie and gelatin capsules for yeast overgrowth"
- "Suggested Use for Best Results: 1. Take one oral capsule daily (green label bottle), just before a light meal . . . 2) Insert one capsule vaginally daily (pink label bottle), before bedtime"

The following statements from your package labeling and insert document the intended use of the Gy-Na-Tren product (vaginal capsules) to affect the structure or function of the human body:

Outer carton labeling:

- "scientifically proven to promote a positive balance in the vaginal and intestinal ecology when taken as directed"

Insert Labeling:

- "Megadophilus vaginal caps taken on a daily basis provide billions of colony-forming units of *L. acidophilus* NAS super strain – considered by the scientific community to assist in providing a positive balance in vaginal flora."

Life Start

According to your website, Life Start is a milk-based probiotic product for infants containing the bacterium "*Bifidobacterium infantis*." The product is labeled as a dietary supplement and sold in powder form. The following statements from your website document the intended use of the Life Start product as a human drug:

- "When given right before birth, helps to establish an optimal flora found to be a key component in helping to deter predisposition to allergies and asthma . . . ."
- "When to Use Life Start . . . After antibiotic therapy . . . ."

While your website and other labeling represent Gy-Na-Tren, including both the oral and vaginal preparations, and Life Start as dietary supplements, the labeling statements quoted above make clear that Gy-Na-Tren, promoted for yeast overgrowth, and Life Start, promoted to prevent allergies and asthma and for use during infections in conjunction with antibiotics, are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Therefore, these products meet the definition of a drug and are subject to regulation as such. Additionally, the route of administration of the vaginal Gy-Na-Tren capsule eliminates this product from the dietary supplement definition found in 21 U.S.C. § 321(ff)(2)(A)(i) of the Act , to mean a product that is

intended for ingestion. Accordingly, Gy-Na-Tren and Life-Start are drugs as defined by section 201(g)(1) of the Act, 21 U.S.C. § 321(g)(1). Furthermore, Gy-Na-Tren and Life Start are new drugs under section 201(p) of the Act, 21 U.S.C. § 321(p) because they are not generally recognized by qualified scientific experts as safe and effective for their labeled uses. The disclaimer on Gy-Na-Tren's labeling stating that it is not intended to diagnose, treat, cure, or prevent any disease, does not alter the fact that the claims made for your product in its labeling, including your website, cause it to be a drug as defined by section 201(g)(1) of the Act, 21 U.S.C. §321(g)(1). As new drugs, Gy-Na-Tren and Life Start may not be legally marketed in the United States because neither product is the subject of an approved application as required by Section 505 of the Act, 21 U.S.C. § 355.
Furthermore, Gy-Na-Tren is misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o) because it is not manufactured, prepared, propagated, compounded or processed in an establishment duly registered under section 510 of the Act, 21 U.S.C. § 352(o), nor is it included in a list required by section 510(j) of the Act, 21 U.S.C. § 360(j).

ANIMAL DRUG PRODUCTS

CanineDophilus, FelineDophilus, and EquiFlora

The statements noted below appear on your website and document the intended uses of your animal drugs.

The following statements from your website document the intended use of CanineDophilus to prevent and treat disease in animals as well as affect the structure or function of the animal body:

- "gently restore the beneficial intestinal bacteria in small and large animals"
- "They will help alleviate numerous problems, including bad breath, poor digestion, diarrhea and flatulence . . . ."
- "When highly potent probiotics containing billions of cfu are fed to the animal, the probiotics outgrow the undesirable bacteria on the wall of the intestine, forcing the bad bacteria off the intestine walls and out of the body."

The following statements from your website document the intended use of FelineDophilus and Equiflora to affect the structure or function of the animal body:

FelineDophilus: "will help cats process hairballs through normal elimination."
EquiFlora: "useful for horses especially during periods of stress such as: racing, eventing, breaking, before and after transport, extreme weather exposure, following surgery, after vaccination and with dietary changes."

Next, CanineDophilus, FelineDophilus, and EquiFlora are new animal drugs under section 201(v) of the Act, 21 U.S.C. § 321 (v), because they are not generally recognized by qualified scientific experts as safe and effective for their labeled uses.

CanineDophilus, FelineDophilus, and Equiflora are unsafe under section 512(a)(1) of the Act, 21 U.S.C. § 360b(a)(1), because they are new animal drugs for which your firm does not have an approved application. Because they are unsafe under section 512 of the Act, 21 U.S.C. § 360b, they are adulterated under section 501(a)(5) of the Act, 21 U.S.C. § 351(a)(5). Furthermore, the agency has concluded that the Dietary Supplement Health and Education Act of 1994 does not apply to products intended for use in animals, see 61 Fed. Reg. 17706 (Apr. 22, 1996).

This letter is not intended to be an all-inclusive review of the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct the noted violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. In addition, federal agencies are advised of the issuance of Warning Letters pertaining to drugs so that they can consider this information when awarding contracts.

Please notify this office in writing within fifteen working days of receipt of this letter of the specific steps that you have taken to correct the noted violations, including an explanation of steps taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to:

Pamela B. Schweikert
Director, Compliance Branch
U.S. Food & Drug Administration
19701 Fairchild
Irvine, CA 92612

Sincerely,

Alonzo E. Cruse
District Director